

Sub E5

- b) applying the homogeneous solution into the area of skin to be treated; and
- c) evaporating the volatile solvent from the homogeneous solution;

wherein the volatile solvent is present in the formulation in amounts between 40-80%

wherein the anesthetic is a eutetic mixture of lidocaine and prilocaine.

Please add the following claim:

Sub E5

- 15. The method according to claim 1, wherein said volatile penetration enhancing agent is selected from the group consisting of isopropyl alcohol and denatured ethyl alcohol.

REMARKS

Applicant wishes to thank the Examiner in charge of this application, Ms. Vicki Kim, for the courtesy and cooperation she extended Applicant's undersigned counsel during the telephone interview kindly granted on November 8, 2002. During this interview, Applicant's counsel discussed a proposed Amendment, which had previously been sent to Ms. Kim by telefax on October 7, 2002. The Examiner made a number of constructive suggestions as to the wording of the independent claims and requested that Applicant file a "Continued Prosecution Application" so that

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Supplemental Amendment C

Attorney Docket: 3863.015

Applicant's Amendment B, Declaration under 37 CFR 1.132, and the Examiner's suggested claim amendment may be entered in the case.

Accordingly, a CPA is being filed so that Applicant's proposed amendment (submitted as Amendment B) may be entered and formally considered by the Examiner.

Claims 1, 9, and 13-14 have been amended as suggested by the Examiner by adding the limitation of the type of lipophilic base that can be used in the present invention. Adding this limitation to the claims further differs the present invention from the Sipos reference.

No new matter is introduced by these amendments.

The filed Declaration clearly demonstrates that the Castillo reference does not evaporate.

Applicant is also including a Supplemental Declaration under 37 CFR 1.132 including the information requested by the Examiner.

Applicant would also like to point out to the Examiner that all independent claims require the formation of a homogenous solution. As can be seen from the filed Declaration, the Sipos reference does not provide a homogenous solution as required by the present claims.

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Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned for a telephone interview at the indicated telephone number, or at defillo@patentcentral.com.

Respectfully submitted,


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Date: **November 29, 2002**

VERSION WITH MARKINGS TO SHOW CHANGES MADE HEREBY ATTACHED

The Examiner is requested to accept the marked-up version as it is based on the previous version, which when modified as below, produces the clean version submitted with the current amendment.

Please amend Claims 1, 9, and 13-14 as follows:

1. (Twice amended) A method for applying a topical anesthetic to an area of skin, the method comprising the steps of:

- a) forming a homogeneous solution by incorporating into a volatile solvent an anesthetic in a lipophilic base, the lipophilic base selected from the group consisting of White Ointment USP, Yellow Ointment NF, Oleic Acid USP, Olive Oil USP, Paraffin USP, Petrolatum NF, White Petrolatum USP, Spermaceti Wax USP, Synthetic Spermaceti NF, Starch Glycerite NF, White Wax USP, and Yellow Wax USP [into a volatile solvent to form a homogeneous solution];
- b) applying the homogeneous solution into the area of skin to be treated; and
- c) evaporating the volatile solvent from the homogeneous solution;

wherein the volatile solvent is present in the formulation in amounts between 40-80%

[wherein said volatile solvent is selected from the group consisting of isopropyl alcohol and denatured ethyl alcohol].

9. (Twice amended) A method for applying a topical anesthetic to an area of skin, the method comprises the steps of:

a) mixing from about 40-80% of alcohol with a mixture containing:

from about 3-40% of lidocaine;

from about 0.5 to about 2.0%, preferably about 1.5% thickener;

from about 0.5 to about 2.0%, preferably about 1.5% emulsiifer; and

the balance being a lipophilic base selected from the group consisting of White Ointment USP, Yellow Ointment NF, Oleic Acid USP, Olive Oil USP, Paraffin USP, Petrolatum NF, White Petrolatum USP, Spermaceti Wax USP, Synthetic Spermaceti NF, Starch Glycerite NF, White Wax USP, and Yellow Wax USP;

b) applying the homogeneous solution into the area of skin to be treated; and

c) evaporating the volatile solvent from the homogeneous solution;

wherein said topical anesthetic rapidly penetrates the skin surface at said skin

[wherein said volatile solvent is selected from the group consisting of isopropyl alcohol and denatured ethyl alcohol].

13. (Twice amended) A method of obtaining topical anesthesia in mammals by way of topical application, said method comprising administering a formulation comprising a mixture of lidocaine in a lipophilic base dissolved in 40-80% alcohol, wherein the lipophilic base is selected from the group consisting of White Ointment USP, Yellow Ointment NF, Oleic Acid USP, Olive Oil USP, Paraffin USP, Petrolatum NF, White Petrolatum USP, Spermaceti Wax USP, Synthetic Spermaceti NF, Starch Glycerite NF, White Wax USP, and Yellow Wax USP;

[said alcohol is selected from the group consisting of isopropyl alcohol and denatured ethyl alcohol].

14. (Twice amended) A method for applying a topical anesthetic to an area of skin, the method comprising the steps of:

- a) forming a homogeneous solution by incorporating into a volatile solvent an anesthetic in a lipophilic base, the lipophilic base selected from the group consisting of White Ointment USP, Yellow Ointment NF, Oleic Acid USP, Olive Oil USP, Paraffin USP, Petrolatum NF, White Petrolatum USP, Spermaceti Wax USP, Synthetic Spermaceti NF, Starch Glycerite NF, White Wax USP, and Yellow Wax USP [into a volatile solvent to form a homogeneous solution];

- b) applying the homogeneous solution into the area of skin to be treated; and
- c) evaporating the volatile solvent from the homogeneous solution;

wherein the volatile solvent is present in the formulation in amounts between 40-80%

[wherein said volatile solvent is selected from the group consisting of isopropyl alcohol and denatured ethyl alcohol]

wherein the anesthetic is a eutetic mixture of lidocaine and prilocaine.

Please add the following claim:

--15. The method according to claim 1, wherein said volatile penetration enhancing agent is selected from the group consisting of isopropyl alcohol and denatured ethyl alcohol.--

Lack of Art.